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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,535	07/09/2001	James C. Keith JR.	GIN-6006B4	6877

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	8

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,535	KEITH ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 19-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

1. Applicant's election of group VI, claims 8-18 (drawn to methods for diagnose preeclampsia by detecting the presence or level of syncytin polypeptide) in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for of determining whether a human subject is at risk of developing preeclampsia by detecting a decrease in the level of syncytin polypeptide in placental tissue or by detecting an increase in syncytin polypeptide in serum, relative to a normal control sample, does not reasonably provide enablement for methods for determining whether any subject is at risk of developing preeclampsia by detecting the presence or level of syncytin in any biological sample . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands,* 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the

invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

The claims are drawn to methods for determining whether a subject is at risk for developing preeclampsia comprising detecting the presence or level of syncytin polypeptide in a biological sample from the subject as indicative of risk for developing preeclampsia. The specification (see, for example, pages 30-31) teaches that syncytin mRNA levels in samples obtained from placental tissue are significantly decreased in pregnant women having preeclampsia as compared to normal/control pregnant women. The specification (page 32) also teaches that, in women with preeclampsia, the syncytin protein is localized improperly to the apical membrane of the synctiotriophoblast, whereas in control samples from pregnant women, the syncytin protein is localized to the basal membrane of the syncytiotrophoblast. Additionally, the specification (pages 32-33) teaches that serum syncytin protein levels were increased in subjects with preeclampsia versus normal pregnant women.

The specification is not enabling for the invention as it is broadly claimed for the following reasons: Firstly, the claims include methods in which the presence of syncytin protein is detected as indicative of preeclampsia. However, the specification has not established that the presence of syncytin is correlated with the occurrence of preeclampsia. The specification (page 4) teaches that syncytin is detectable only in placental tissues. The specification does not teach that any other tissues of the body express syncytin. Since the expression of this protein is so limited, it is highly unpredictable as to whether syncytin would be expressed in other biological tissues and it is unpredictable as to whether the presence of the protein alone would be indicative

of preeclampsia. Secondly, the specification has not enabled methods in which any biological sample is analyzed as a means for determining risk of developing preeclampsia. Again, the specification teaches that syncytin is expressed only in placental tissue. There is no evidence provided in the specification as to the presence or level of syncytin in other tissue types, including any endothelial cell sample and any tumor sample. Additionally, the specification does not provide any information regarding the presence or level of syncytin protein in amniotic fluid or chorionic fluid samples. Thirdly, the specification does not enable methods which generically teach the level of syncytin protein in a biological sample. As discussed above, the specification teaches that syncytin protein is expressed at lower levels in placental tissue and at higher levels in serum of women with preeclampsia versus normal pregnant women. These conflicting results obtained with syncytin protein expression make it difficult to reasonably predict whether syncytin protein levels will be increased or decreased in other biological samples. The findings provided in the specification exemplify the unpredictability in the art and demonstrate that the findings obtained with one biological sample cannot be obtained to other types of biological samples. Lastly, the specification provides information regarding the expression of syncytin only in placental and serum samples of pregnant women. The specification does not provide any information regarding syncytin expression patterns in non-humans. It is unpredictable as to whether other syncytin protein is correlated with preeclampsia in other organisms and it is unclear as to whether the levels of syncytin increase or decrease during pregnancy in biological samples from non-humans. law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher,*

427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the state of the art indicates that it is highly unpredictable as to whether syncytin levels are modified in other biological samples and it is unpredictable as to whether syncytin is expressed in tissues other than placenta in women with preeclampsia versus normal pregnant women. Insufficient guidance has been provided in the specification for practicing the method as it is broadly claimed to include methods in which any biological sample is analyzed for the presence or level of syncytin protein as indicative of preeclampsia. Accordingly, in view of the lack of guidance provided in the specification and in view of the unpredictability in the art, undue experimentation would be required to practice the invention as it is broadly claimed.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Travis (Science News, May 2000) teaches that humans and certain primates have the syncytin gene, but that mice and other mammals do not appear to have this gene. The reference also states that researchers are examining the role of syncytin and pregnancy by comparing the production of syncytin healthy and abnormal placental tissue. However, Travis does not provide the results of these studies and specifically does not teach that or suggest methods of diagnosing

preeclampsia by detecting a decrease in the level of syncytin protein in placental tissues or an increase in the level of syncytin in serum samples.

Mi (Nature (Feb 2000) 402: 785-789) teaches the amino acid sequence of syncytin protein. The reference (page 786) teaches that 2 major transcripts for syncytin were detected in placental tissues, but that syncytin is not expressed in any other human tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

December 19, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER